AUTHORITY: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395hh); Pub. L. 110–149, 121 Stat. 1820.

EFFECTIVE DATE NOTE: At 76 FR 15126, Mar. 18, 2011, the authority citation for part 488 was revised, effective Jan. 1, 2012. For the convenience of the user, the added and revised text is set forth as follows:

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)

SOURCE: 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 488.1 Definitions.

As used in this part—

Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with § 488.5 or § 488.6.

Act means the Social Security Act.

AOA stands for the American Osteopathic Association.

Certification is a recommendation made by the State survey agency on

the compliance of providers and suppliers with the conditions of participation, requirements (for SNFs and NFs), and conditions of coverage.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Full review means a survey of a hospital for compliance with all conditions of participation for hospitals.

JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations.

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

Provider of services or *provider* means a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to CMS's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by CMS, taken as a whole.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

Supplier means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

Validation review period means the one year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006]

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.
1128A—Civil money penalties.
1814—Conditions for, and limitations on, payment for Part A services.
1819—Requirements for SNFs.
1861(f)—Requirements for psychiatric hospitals.
1861(z)—Institutional planning standards that hospitals and SNFs must meet.